

REMARKS

Upon entry of the present amendment, claims 1-27 are pending in the instant application. Claims 1-4, 6, 7, 9, 11, 13, and 15-20 have been amended, and claims 21-27 have been added. Support for the amendments presented herein is found throughout the specification and in the claims as originally filed. For example, support for the rigid fibers recited by amended claims 1, 6, 7, 9, 11 and 13 is found at least at page 8, line 29 through page 9, line 3; at page 13, lines 21-24 and at page 17, lines 14-31. Support for the fibers recited by amended claims 15-20 is found at least at page 4, lines 1-6. Support for the fibers recited by new claims 21-27 is found at least at page 9, lines 17-18. Claims 2-4 have been amended solely to correct inadvertent typographical errors and to maintain antecedent basis throughout the amended claims. Accordingly, no new matter has been added these amendments.

Double Patenting

Claims 1-5, 7 and 15-20 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,712,610 (“the ‘610 patent”).

Applicants submit herewith a terminal disclaimer over the ‘610 patent. Accordingly, Applicants request that the Examiner withdraw this double-patenting rejection.

Claim Objections

Claims 3, 4, 9, 11 and 13 have been objected to because of informalities contained therein. In particular, the Examiner has objected to the typographical error in “tetracycline” in claim 3 and to the recitation of the terms “the antibiotic” (claims 4 and 9), “the root canal” (claim 9), and “the treatment site” (claims 9, 11 and 13).

Claim 3 has been amended herein to correct the inadvertent typographical error in the term “tetracycline”. In addition, claims 4, 9, 11 and 13 have been amended to maintain antecedent basis throughout the claims. Accordingly, withdrawal of these objections is requested.

Claim Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 2, 3, 5 and 15-18 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite. According to the Examiner, claim 2 contains an improper Markush expression, and the term “percent” recited by claims 15-18 is unclear.

The Markush expression recited by claim 2 has been amended herein. In addition, claims 15-18 have been amended to recite that the percentage of vinyl acetate refers to the percentage by weight. Thus, Applicants respectfully request that the Examiner withdraw these objections.

Claim Rejections Under 35 U.S.C. §102(b)

Claims 1-3, 5 and 6 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,892,736 by Goodson (“Goodson”). According to the Examiner, Goodson describes a “fiber comprising a copolymer vehicle having incorporated therein one or more medicaments”. (Office Action, page 3).

Independent claim 1 has been amended to recite an endodontic fiber suitable for the local delivery and sustained release of one or more medicaments incorporated therein to an intracanal treatment site, wherein the fiber comprises a rigid copolymer vehicle having incorporated therein one or more medicaments, wherein the fiber has a size and shape suitable for placement in a root canal.

Independent claim 6, as amended, is directed to a modified periodontal fiber suitable for the delivery and sustained release of medicament incorporated therein to an intracanal treatment site, wherein the fiber comprises a rigid copolymer vehicle having incorporated therein one or more medicaments, wherein the copolymer is treated to decrease its surface tackiness and wherein the fiber has a size and shape suitable for placement in a root canal.

Thus, these amended claims and their respective dependent claims (including claims 2-3 and 5) are directed to rigid fibers having one or more medicaments incorporated therein.

Goodson, in contrast, does not disclose or suggest rigid fibers. In fact, the fibers described by Goodson must be “sufficiently flexible and formable to conform readily to the periodontal site to be treated”. (See Goodson at col. 3, lines 32-33). Accordingly, this reference does not disclose every element of the fibers recited by amended claims 1-3, 5 and 6. Thus, the

claimed fibers are not anticipated by the teachings of Goodson, and this rejection should be withdrawn.

Claim Rejections Under 35 U.S.C. §103(a)

Claim 4

Claim 4 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Goodson in view of U.S. Patent No. 5,114,718 by Damani (“Damani”). In particular, the Examiner has stated that “it would have been obvious to one having ordinary skill in the art to incorporate medicament of clindamycin to the fiber of Goodson, since Damani discloses both as known antibiotics”. (Office Action, page 4).

Claim 4 depends independent claim 1 and, therefore, contains all of the limitations recited by amended claim 1. As described above, claim 1 has been amended to recite an endodontic fiber suitable for the local delivery and sustained release of one or more medicaments incorporated therein to an intracanal treatment site, wherein the fiber comprises a rigid copolymer vehicle having incorporated therein one or more medicaments, wherein the fiber has a size and shape suitable for placement in a root canal. Thus, claim 4 is also directed to rigid fibers comprising an ethylene vinyl acetate copolymer having a diameter of from about 0.1 mm to about 2.0 mm and the medicament is clindamycin incorporated at a dose of about 2.0 mg to about 5.0 mg per 10mm of fiber.

As described above, the Goodson reference does not teach or suggest a rigid fiber. Moreover, the addition of the Damani reference fails to cure the deficiencies in the teachings of Goodson, as Damani does not describe or suggest a rigid fiber. In contrast to the rigid fiber recited by claim 4, the fibers described by Damani are “flexible and solid”. (See Damani at col. 2, lines 29-31). Thus, Goodson and Damani, alone or in combination, do not teach or suggest a rigid fiber. Accordingly, these references do not render the fibers of the claimed invention obvious. Applicants request, therefore, that the Examiner withdraw this rejection.

Claims 7-14

The Examiner has rejected claims 7-14 as being unpatentable over Goodson. According to the Examiner, “one skilled in the art would recognize that the fiber of Goodson is of a size

and characteristics sufficient for positioning in a root canal and Goodson shows methods method of localized treatment with the oral cavity.” (Office Action, page 4).

Claim 7 has been amended to recite a method for the local delivery and sustained release of a medicament to an intracanal treatment site by (a) obtaining an endodontic fiber suitable for intracanal use having one or more medicaments incorporated therein, wherein said endodontic fiber comprises a rigid copolymer; (b) positioning the fiber of (a) in the root canal such that the fiber is in direct contact with the treatment site; and (c) maintaining the fiber at the treatment site, wherein the medicament is delivered to the treatment site at a controlled rate.

As amended, claim 9 is directed to a method of treating an endodontic bacterial infection comprising the steps of (a) obtaining an endodontic fiber suitable for intracanal use having one or more medicaments incorporated therein, wherein said endodontic fiber comprises a rigid copolymer; (b) inserting the fiber of (a) into a root canal such that the fiber is in direct contact with a treatment site in the root canal; and (c) maintaining the fiber at the treatment site, wherein the antibiotic is delivered to the treatment site.

Amended claim 11 recites a method of disinfecting a root canal receiving endodontic treatment by (a) obtaining an endodontic fiber suitable for intracanal use having one or more medicaments incorporated therein, wherein said endodontic fiber comprises a rigid copolymer; (b) inserting the fiber of (a) into a debrided and irrigated root canal such that the fiber is in direct contact with a treatment site in the root canal; and (c) maintaining the fiber at the treatment site, wherein the medicament is administered to the treatment site at a controlled rate.

Claim 13 has been amended to recited a method of reducing inflammation in periapical tissue of a tooth undergoing endodontic treatment by (a) obtaining an endodontic fiber suitable for intracanal use having incorporated therein an anti-inflammatory agent, wherein said endodontic fiber comprises a rigid copolymer; (b) positioning the fiber into a debrided and irrigated root canal such that the fiber is in direct contact with an inflamed tissue in the root canal; and (c) maintaining the endodontic fiber at the treatment site, wherein the anti-inflammatory agent is delivered to the site of inflammation.

Thus, these methods recite the use of a rigid fiber. As described above, Goodson does not disclose or suggest rigid fibers or methods that use rigid fibers. Moreover, the fibers described by Goodson must be “sufficiently flexible and formable to conform readily to the periodontal site to be treated”. (See Goodson at col. 3, lines 32-33). Thus, Goodson explicitly

teaches away from the use of a rigid fiber, and, therefore, a person of ordinary skill in the art would have no motivation from the teachings of Goodson to modify the fibers described therein to generate rigid fibers. As such, the methods of the claimed invention are not obvious over the teachings of the Goodson reference, and this rejection should be withdrawn.

Claims 15-20

Claims 15-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Goodson in view of U.S. Patent No. 4,003,810 by Hoyt et al. ("Hoyt"). According to the Examiner, it would have been "an obvious matter of choice to one of ordinary skill in the art as to the specific amount of a known material and as to its intended use". (Office Action, page 5).

Applicants traverse this rejection on the grounds that the Examiner has failed to establish a *prima facie* case of obviousness. A *prima facie* case of obviousness requires some suggestion or motivation, either in the references themselves or in the knowledge generally available in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 706.02(j).

Claims 15-20 have been amended to depend from independent claim 1 and, therefore, contain all of the limitations recited by amended claim 1. As described above, claim 1 has been amended to recite an endodontic fiber suitable for the local delivery and sustained release of one or more medicaments incorporated therein to an intracanal treatment site, wherein the fiber comprises a rigid copolymer vehicle having incorporated therein one or more medicaments, wherein the fiber has a size and shape suitable for placement in a root canal. Thus, amended claims 15-20 are also directed to rigid fibers having one or more medicaments incorporated therein, wherein the fiber comprises an ethylene vinyl acetate copolymer comprising less than 20% vinyl acetate by weight.

As described above, Goodson does not disclose or suggest rigid fibers or methods of using rigid fibers. Moreover, this reference does not disclose or suggest fibers that comprise an ethylene vinyl acetate copolymer having less than 20% vinyl acetate by weight. In contrast to the fibers recited by amended claims 15-20, the Goodson fibers contain 45% vinyl acetate by weight. As Goodson explicitly requires that the fibers are "sufficiently flexible and formable to

conform readily to the periodontal site to be treated” (col. 3, lines 32-33), a person of ordinary skill in the art would not have been motivated by the teachings of Goodson to modify the fibers described therein to produce rigid fibers. Thus, one of ordinary skill in the art would have no motivation to combine the Goodson fibers with the fibers described in the Hoyt reference.

The fact that references can be combined or modified does not render the resulting combination obvious unless the prior art also suggests the desirability of the combination. (*See* MPEP §2143.01, citing *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)). However, there is no suggestion in the Goodson reference that would motivate a skilled artisan to modify the fibers described therein to contain less than 20% EVA to produce a rigid fiber. Thus, the fact that the Goodson and Hoyt references can be combined is not sufficient to establish a *prima facie* case of obviousness.

Moreover, an assertion that modifying the Goodson reference would have been within the ordinary skill of the art at the time the claimed invention was made because the cited references were individually known in the art at the time the instant application was filed is also insufficient to establish a *prima facie* case of obviousness without some objective reason to combine the references. (*See* MPEP §2143.01, citing *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pate. App. & Inter. 1993)). Thus, the fact that the Goodson and Hoyt references were known in the art individually at the time the instant application was filed does not render the claimed fibers obvious, as there is no teaching or suggestion in the Goodson reference that would motivate one of ordinary skill in the art to modify the fibers described therein.

Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, and this rejection should be withdrawn.

CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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